

### **Remarks**

Claims 1 to 23 are pending.

The Examiner has acknowledged that the specification has been amended to cross reference 09/589,580 filed June 7, 2000, now U.S. Patent No. 6,451,810 and provisional application 60/138,365. To assure inclusion of this in the application, Applicants respectfully request that the above amendment to the specification be entered.

### **Information Disclosure Statement**

The Examiner has indicated that the information disclosure statements received by the USPTO on 16 July 2002 and 13 September 2002 have been considered. However, the Examiner has pointed out that in the information disclosure statement of 16 July 2002, the entry of Baranov, et al. appears to have the wrong abstract number. Applicants have reviewed this entry and found that an unintentional typographical error was made. The entry should read:

Baranov, et al., Chem. Abs. 85, 94362, (1976).

A copy of this reference was included with the information disclosure statement. With this clarification, applicants respectfully request that the Examiner initial this entry and provide Applicants with a copy of the initialed PTO-1449.

### **§ 112 Rejections**

Claims 18-23 stand rejected under 35 USC § 112, first paragraph, on the grounds that the specification, while being enabling for a method of inducing biosynthesis of interferon alpha or tumor necrosis factor, allegedly does not reasonably provide enablement for the use of the compositions for inducing biosynthesis of other cytokines, and allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

This rejection is traversed. Reconsideration of and removal of this rejection is respectfully requested.

Regarding claims 18-23 directed to a method of inducing cytokine biosynthesis in an animal comprising administering an effective amount of a composition of claim 1, 4, 13, 15, 16, or 17, the specification provides sufficient information to enable those skilled in the art to use the inventive

compositions not only for biosynthesis of IFN- $\alpha$  or TNF- $\alpha$ , but also for IL-1, 6, 10, and 12, and a variety of other cytokines. (See, for example, page 30, lines 15 through 17.) Further guidance on how to accomplish this is provided, for example, on page 29, lines 25 through 32, and on page 30, lines 1 through 7.

In addition, those skilled in the art of cytokine biosynthesis have known that IFN- $\alpha$  directly or indirectly up-regulates the activity of other cytokines, for example, IFN- $\gamma$ , IL-1, IL-1R, IL-2, IL-2R, IL-6, IL-8, IL-12, IL-15, IL-18R, and ISG-15. This is discussed on pages 566, second column, and 567, first column of a recent review (Brassard et al., *J. Leukocyte Biology*, 71, 565-581 (2002)), **Exhibit A**, which provides eight references dated 1993-1999 from which these and other examples were taken.

Essentially all of the approximately 150 Examples explicitly provided and tested by Applicants showed IFN- $\alpha$  induction. Therefore, given the level of skill in the art, including that discussed above, sufficient direction and guidance has been provided in the specification for one skilled in the art to practice the full scope of the methods as claimed for inducing cytokine biosynthesis using the compositions of the present invention.

Accordingly, Applicants respectfully request that the 35 U.S.C. § 112, first paragraph, rejection of claims 18-23 be withdrawn.

### **§ 102 Rejections**

Claims 1-3 and 18 stand rejected under 35 USC § 102(e) as being anticipated by U.S. Patent No. 6,069,149.

This rejection is traversed. Reconsideration of and removal of this rejection is respectfully requested.

All of the 1*H*-imidazo[4,5-*c*]quinolin-4-amines disclosed in 6,069,149 which include an amide moiety in the substituent at the 1-position also include an -N(CH<sub>3</sub>)CH<sub>3</sub> substituent in the group corresponding the R<sub>4</sub> group of the present invention. Furthermore, the meaning of “substituted aryl”, defined on page 29 of the present specification does not include -N(CH<sub>3</sub>)CH<sub>3</sub>. Applicants, therefore, submit that claims 1-3 and 18 are not anticipated by U.S. Patent No. 6,069,149. Accordingly, Applicants respectfully request that the rejection of claims 1-3 and 18 under 35 USC § 102(e) be withdrawn.

**Obviousness-Type Double Patenting**

Claims 1, 3-7, 9-11, 15, 16, 18, and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-3, 8, 20-23, 29-32, 43-45, and 48 of U.S. Patent No. 6,451,810. . Included herewith is a terminal disclaimer in compliance with 37 CFR 1.321(c) and 37 CFR 3.73(b). Applicants, therefore, respectfully request that this rejection be withdrawn.

**Claim Objections**

Claims 8 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. However, since the rejection of the claims from which 8 and 12 depend, namely claims 5 and 9, has been overcome, Applicants respectfully request that this objection be withdrawn.

**Allowable Subject Matter**

The Examiner has indicated that claims 13, 14, and 17 are allowable.

In view of the above, it is submitted that the application is in condition for allowance. Reconsideration of the application is requested. Allowance of claims 1-23 at an early date is solicited.

Respectfully submitted,

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Date

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